Complete Summary

GUIDELINE TITLE

Surgical alternatives to hysterectomy in the management of leiomyomas.

BIBLIOGRAPHIC SOURCE(S)

American College of Obstetricians and Gynecologists (ACOG). Surgical alternatives to hysterectomy in the management of leiomyomas. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2000 May. 10 p. (ACOG practice bulletin; no. 16). [64 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Surgical alternatives to hysterectomy in the management of leiomyomas. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 1994 May. (ACOG educational bulletin number 192).

According to the guideline developer, this guideline is still considered to be current as of December 2005, based on a review of literature published that is performed every 18-24 months following the original guideline publication.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Uterine leiomyomas (fibroids)

GUIDELINE CATEGORY

Evaluation
Management
Treatment

CLINICAL SPECIALTY

Internal Medicine
Obstetrics and Gynecology
Surgery

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To aid practitioners in making decisions about appropriate obstetric and gynecologic care
- To review the literature about surgical alternatives to hysterectomy and to offer treatment recommendations

TARGET POPULATION

Women with uterine leiomyomas

INTERVENTIONS AND PRACTICES CONSIDERED

Treatment/Management

Surgical Alternatives to Hysterectomy

1. Abdominal myomectomy
2. Laparoscopic myomectomy
3. Hysteroscopic myomectomy
4. Endometrial ablation

Note: Innovative procedures, including uterine artery embolization and myolysis, and medical treatment options, including progesterone antagonist mifepriston (RU 486) and gonadotropin-releasing hormone (GnRH) antagonists, were discussed but not recommended, as further research is needed.

Adjunctive Medical Treatment

1. Preoperative adjuvant therapy: Gonadotropin-releasing hormone agonists
2. Intraoperative adjuvant therapy: Vasopressin

MAJOR OUTCOMES CONSIDERED

- Morbidity and mortality

- Recurrence of leiomyomas
- Risk of follow-up treatment, including unplanned hysterectomy

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The MEDLINE database, the Cochrane Library, and the American College of Obstetricians and Gynecologists' (ACOG's) own internal resources were used to conduct a literature search to locate relevant articles published between January 1985 and May 1999. Priority was given to articles reporting results of original research, although review articles and commentaries also were consulted. Abstracts of research presented at symposia and scientific conferences were not considered adequate for inclusion in this document.

Guidelines published by organizations or institutions such as the National Institutes of Health and the American College of Obstetricians and Gynecologists were reviewed, and additional studies were located by reviewing bibliographies of identified articles.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force.

I Evidence obtained from at least one properly designed randomized controlled trial

II-1 Evidence obtained from well-designed controlled trials without randomization

II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group

II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.

III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Analysis of available evidence was given priority in formulating recommendations. When reliable research was not available, expert opinions from obstetrician-gynecologists were used. See also the "Rating Scheme for the Strength of Recommendations" field regarding Grade C recommendations.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories:

Level A - Recommendations are based on good and consistent scientific evidence.

Level B - Recommendations are based on limited or inconsistent scientific evidence.

Level C - Recommendations are based primarily on consensus and expert opinion.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Practice Bulletins are validated by two internal clinical review panels composed of practicing obstetrician-gynecologists generalists and sub-specialists. The final guidelines are also reviewed and approved by the American College of Obstetricians and Gynecologists (ACOG) Executive Board.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The grades of evidence (I-III) and levels of recommendations (A-C) are defined at the end of "Major Recommendations."

The following recommendations are based on good and consistent scientific evidence (Level A):

- In women with symptomatic leiomyomas, hysterectomy provides a definitive cure.
- In women with symptomatic leiomyomas, abdominal myomectomy is a safe and effective option for women who wish to retain their uterus. If this option is selected, women should be counseled preoperatively about the relatively high risk of reoperation.
- Use of gonadotropin-releasing hormone (GnRH) agonists preoperatively is beneficial, especially when improvement of hematologic status and uterine shrinkage are important goals. Benefits of the use of GnRH agonists should be weighed against their cost side effects for individual patients.
- The use of vasopressin at the time of myomectomy appears to limit blood loss.

The following recommendation is based on limited or inconsistent scientific evidence (Level B):

- The clinical diagnosis of rapidly growing leiomyomas has not been shown to predict uterine sarcoma and thus should not be used as the sole indication for myomectomy or hysterectomy.

The following recommendations are based primarily on consensus and expert opinion (Level C):

- Laparoscopic myomectomy appears to be a safe and effective option for women with a small number of moderately sized uterine leiomyomas who do not desire future fertility. Further studies are necessary to evaluate the safety of this procedure for women planning pregnancy.
- Hysteroscopic myomectomy is an effective option for controlling menorrhagia in women with submucosal leiomyomas.
- Although endometrial ablation appears to be an effective option in controlling menorrhagia in women without leiomyomas, further studies are needed in women who have clinically significant leiomyomas.
- Because leiomyomas may be a factor in infertility for some patients, the issues are complex, and myomectomy should not be performed without first completing a comprehensive fertility evaluation.

- Although postmenopausal women with leiomyomas may have more bleeding problems and some increase in leiomyoma size while taking hormone replacement therapy, there appears to be no reason to withhold this treatment option from women who desire or need such therapy.

Definitions:

Grades of Evidence

I Evidence obtained from at least one properly designed randomized controlled trial

II-1 Evidence obtained from well-designed controlled trials without randomization

II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group

II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.

III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

Levels of Recommendations

Level A - Recommendations are based on good and consistent scientific evidence.

Level B - Recommendations are based on limited or inconsistent scientific evidence.

Level C - Recommendations are based primarily on consensus and expert opinion.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Overall Benefits

Appropriate management of uterine leiomyomas

Benefits of Specific Treatments

- Abdominal myomectomy: Clinical experience and pooled results of numerous small studies suggest that there is excellent resolution of menorrhagia symptoms (overall 81% resolution; range, 40 to 93%) with similar results for resolution of pelvic pressure with abdominal myomectomy.
- Laparoscopic myomectomy minimizes the size of the abdominal incision, although it usually requires a minimum of three small incisions.
- Hysteroscopic myomectomy. Several series of between 100 and 200 patients undergoing hysteroscopic myomectomies with good results have been published. For women desiring pregnancy, fertility rates appear good; 59% of patients with submucosal leiomyomas conceived after hysteroscopic myomectomy.
- Gonadotropin-releasing hormone (GnRH) agonists: These medications are very effective in inducing amenorrhea and causing uterine shrinkage in a large proportion of women who take them. When a significant reduction in uterine volume is necessary to achieve surgical goals (e.g., when the patient prefers a low-transverse incision instead of a vertical incision or an endoscopic procedure), GnRH agonists may be useful. By inducing amenorrhea, GnRH agonists have been shown to improve hematologic parameters, shorten hospital stay, and decrease blood loss, operating time, and postoperative pain when given for 2 to 3 months preoperatively.
- Vasopressin: Several studies suggest that the infiltration of vasopressin into the myometrium decreases blood loss at the time of myomectomy. A study of 20 patients demonstrated that vasopressin significantly decreased blood loss compared with saline injection in a randomized myomectomy study. One study demonstrated that injection of vasopressin into the cervix at the time of operative hysteroscopy decreased blood loss, fluid intravasation, and operative time.

POTENTIAL HARMS

Side Effects of Treatment

- Abdominal myomectomy: In the long term, the risk of formation of new leiomyomas limits the efficacy of myomectomy. A summary of a small case series conducted since the 1920s suggests the risk of follow-up treatment (in this instance, defined as hysterectomy, second myomectomy, or radiation therapy) varied from 3 to 32%, with a mean risk of 15%, although no information on the length of follow-up was given. In a relatively large series (125 patients followed at least 5 years and up to 23 years), there was evidence that recurrence depended on the number of leiomyomas present, with a recurrence risk of 11% for a single myoma and a recurrence risk of 26% with multiple myomas. A more recent study of 80 patients found a similar reoperation rate of 18% after 10 years. The risk of undergoing an unexpected hysterectomy at the time of myomectomy appears to be low with skilled surgical technique, even when uterine size is substantial. There may, however, be higher rates of hysterectomy for surgeons inexperienced in the

procedure. Blood loss and the risk of transfusion may be increased in women with larger uteri.

- Laparoscopic myomectomy: In addition to routine surgical complications, reported complications include a 2 to 8% conversion rate to a more open procedure, the formation of uteroperitoneal fistulas, and the possibility of uterine rupture during a subsequent pregnancy. It appears that the risk of recurrent leiomyomas may be higher after a laparoscopic myomectomy than after a traditional myomectomy, with a 33% recurrence risk at 27 months. Several case reports have demonstrated uterine rupture at 33 to 34 weeks of gestation following laparoscopic myomectomy and myolysis.
- Hysteroscopic myomectomy: In a series in which almost all patients were treated for menorrhagia, 16% of the submucosal resection group ultimately underwent a second surgery after a mean follow-up of 9 years. In a series of 167 patients who were followed for 3 years after hysteroscopic myomectomy plus myolysis, approximately 5% underwent a second surgery.
- Endometrial ablation: Complications with all techniques involving operative hysteroscopy include the risk of injury to intra-abdominal structures either by uterine perforation or secondary to electrical or thermal injury. In addition, there can be significant complications as a consequence of the distending medium used. The uterine vasculature can rapidly absorb the substance distending the uterus. Fatal events have been reported with air embolism using an Nd-YAG laser with saline as the distending medium, as well as with hyponatremic encephalopathy with sorbitol as the distending medium.
- Gonadotropin-releasing hormone (GnRH) agonists are expensive and have significant side effects for most women in the short term and significant effects on bone density if taken over longer periods. One surgical disadvantage to preoperative GnRH agonist therapy is that it may make the leiomyomas softer and the surgical planes less distinct.

QUALIFYING STATEMENTS

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- These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.
- It must be recognized that all surgical alternatives to hysterectomy allow the possibility for new leiomyomas to form, and preexisting leiomyomas that were too small to be detected or were intentionally not removed may exhibit significant growth, necessitating another procedure. Complications of other surgical procedures may lead to an unanticipated hysterectomy.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2000 May (reviewed 2005)

GUIDELINE DEVELOPER(S)

American College of Obstetricians and Gynecologists - Medical Specialty Society

GUIDELINE DEVELOPER COMMENT

Not applicable

SOURCE(S) OF FUNDING

American College of Obstetricians and Gynecologists (ACOG)

GUIDELINE COMMITTEE

American College of Obstetricians and Gynecologists (ACOG) Committee on Practice Bulletins-Gynecology

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

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GUIDELINE AVAILABILITY

Electronic copies: Not available at this time.

Print copies: Available for purchase from the American College of Obstetricians and Gynecologists (ACOG) Distribution Center, PO Box 4500, Kearneysville, WV 25430-4500; telephone, 800-762-2264, ext. 192; e-mail: sales@acog.org. The ACOG Bookstore is available online at the ACOG Web site.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on September 14, 2004. The information was verified by the guideline developer on December 8, 2004.

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